Updated NIH Data Management and Sharing (DMS) Policy Requirements

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What we’ll cover:

- NIH Data Management and Sharing (DMS) Policy
- Preparing DMS plans
- Exceptions and responsible management and sharing
- Budgeting
- Form H requirements

How to get help
NIH has a longstanding commitment to making the results of research available.

The new Data Management and Sharing Policy creates a consistent minimum expectation for all research supported by agency.

NIH Policy Notice NOT-OD-21-013
DMS Policy: Scope

Applies to all research, funded or conducted in whole or in part by NIH, that results in the generation of "scientific data".

"Scientific data" is defined as:

"the recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications."
Potential Examples of Scientific Data

Scientific data will vary depending on the project and the context.

<table>
<thead>
<tr>
<th>Scientific data might include:</th>
<th>Single-cell RNA sequencing (scRNA-seq) of T lymphocytes or other immune cells in a study of HIV/AIDS</th>
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<tbody>
<tr>
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<td>Electrophysiological recordings and fMRI images in a study of a rodent model of PTSD</td>
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<td>Step activity from a wearable device in a study of cardiovascular health</td>
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Exclusions from the DMS Policy

Scientific data do not include:

• Data not necessary for or of sufficient quality to validate and replicate research findings,
• Laboratory notebooks,
• Preliminary analyses,
• Completed case report forms,
• Drafts of scientific papers,
• Plans for future research,
• Peer reviews,
• Communications with colleagues, or
• Physical objects, (e.g., laboratory specimens)
# Activities Subject to the DMS Policy

<table>
<thead>
<tr>
<th>APPLIES TO...</th>
<th>DOES NOT APPLY TO...</th>
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<tbody>
<tr>
<td>All research generating scientific data, including but not limited to:</td>
<td>research projects not generating scientific data or non-research projects, including but not limited to:</td>
</tr>
<tr>
<td>• Research Projects</td>
<td>• Training (Ts)</td>
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<td>• Certain Career Development Awards (Ks)</td>
<td>• Fellowships (Fs)</td>
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<td>• Small Business SBIR/STTR</td>
<td>• Certain non-research Career Awards (e.g., KM1)</td>
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<td>• Research Centers</td>
<td>• Construction (C06)</td>
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<td>• Conference Grants (R13)</td>
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<td>• Resources (Gs)</td>
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<td>• Research-Related Infrastructure Programs (e.g., S06)</td>
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Policy Effective Dates

The DMS Policy applies to all NIH funding mechanisms

| Extramural | Competing applications submitted for Jan 25, 2023, and subsequent receipt dates  
- Non-competing awards will not immediately become subject to Policy |
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<tbody>
<tr>
<td>Contracts</td>
<td>Proposals submitted on or after Jan 25, 2023</td>
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<tr>
<td>Intramural</td>
<td>Projects conducted on or after Jan 25, 2023</td>
</tr>
<tr>
<td>Other funding agreements (e.g., Other Transactions)</td>
<td>Executed on or after Jan 25, 2023, unless otherwise stipulated by NIH</td>
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Policy Requirements

1. **Submission** of Data Management & Sharing Plan with all covered funding applications for beginning January 25, 2023

2. **Compliance** with the Data Management and Sharing Plan approved by the funding NIH Institute, Center, or Office for the life of the award
Limitations on Sharing

DMS Plans should maximize appropriate sharing

Justifiable ethical, legal, and technical factors for limiting sharing include:

• Informed consent will not permit or limit scope of sharing or use
• Privacy or safety of research participants would be compromised and available protections insufficient
• Explicit federal, state, local, or Tribal law, regulation, or policy prohibits disclosure
• Restrictions imposed by existing or anticipated agreements with other parties

See Protecting Privacy When Sharing Human Research Participant Data for additional details
Limitations on Sharing: Other Considerations

Reasons **NOT** generally justifiable to limit sharing:

- Data are considered too small
- Researchers anticipate data will not be widely used
- Data are not thought to have a suitable repository
Elements of a DMS Plan

- **Data type**
  - Identifying data to be preserved and shared

- **Related tools, software, code**
  - Tools and software needed to access and manipulate data

- **Standards**
  - Standards to be applied to scientific data and metadata

- **Data preservation, access, timelines**
  - Repository to be used, persistent unique identifier, and when/how long data will be available

- **Access, distribution, reuse considerations**
  - Description of factors for data access, distribution, or reuse

See [Writing a Data Management & Sharing Plan](#) for details
Format of a DMS Plan

- Plans should be no more than 2 pages in length
- Optional format page is available

See [DRAFT Data Management and Sharing Plan](#) for optional template

<table>
<thead>
<tr>
<th>DATA MANAGEMENT AND SHARING PLAN</th>
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<tbody>
<tr>
<td>If any of the proposed research in the application involves the generation of scientific data, this application is subject to the NIH Policy for Data Management and Sharing and requires submission of a Data Management and Sharing Plan. If the proposed research in the application will generate large-scale genomic data, the Genomic Data Sharing Policy also applies and should be addressed in this Plan. Refer to the detailed instructions in the application guide for developing this plan as well as to additional guidance on <a href="http://sharing.nih.gov">sharing.nih.gov</a>. The Plan is recommended to not exceed two pages. Text in italics should be deleted.</td>
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**Element 1: Data Type**

A. Types and amount of scientific data expected to be generated in the project:
Summarize the types and estimated amount of scientific data expected to be generated in the project.

B. Scientific data that will be preserved and shared, and the rationale for doing so:
Describe which scientific data from the project will be preserved and shared and provide the rationale for this decision.

C. Metadata, other relevant data, and associated documentation:
Briefly list the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.

**Element 2: Related Tools, Software and/or Code:**
State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they...
DMS Plan Submission

- A new “Other Plan(s)” field will be added to the PHS 398 Research Plan form to collect a single PDF attachment
- Data Sharing Plans and Genomic Data Sharing Plans will no longer be submitted to the “Resource Sharing Plan(s)” field

See FORMS H: PHS 398 Research Plan for additional details
Sharing Data

Encourages use of established repositories

Depositing data in a quality repository generally improves the FAIRness of data – Findable, Accessible, Interoperable, Reusable

NIH ICs may designate specific data repository(ies)

See Selecting a Data Repository for details
Finding and Selecting a Repository:
Desirable Characteristics for All Data Repositories

- Unique Persistent Identifiers
- Long-Term Sustainability
- Metadata
- Curation and Quality Assurance
- Free and Easy Access
- Broad and Measured Reuse

- Clear Use Guidance
- Security and Integrity
- Confidentiality
- Common Format
- Provenance
- Retention Policy
Finding and Selecting a Repository: NIH & Other Resources

NIH-Supported Repositories

- Filterable list of 70+ NIH Repositories

Other Repository Resources

- Generalist repositories
- Nature's Data Repository Guidance
- Registry of Research Data Repositories

See Repositories for Sharing Scientific Data
When should I share my data?

As soon as possible!

No later than the time of a **publication of findings** in a peer-reviewed journal OR at the **end of the award**, whichever comes first.
Data Management and Sharing Costs

ALLOWABLE COSTS:
- Curating data/developing supporting documentation
- Preserving/sharing data through repositories
- Local data management considerations
- **IMPORTANT:** Must be incurred during the performance period

UNALLOWABLE COSTS:
- Infrastructure costs typically included in indirect costs
- Costs associated with the routine conduct of research (e.g., costs of gaining access to research data)

See *Budgeting for Data Management & Sharing* for details
Submitting DMS Budgets

- Direct costs to support the activities proposed in the DMS Plan must be indicated as “Data Management and Sharing Costs”
  - R&R Budget Form: line item in section F. Other Direct Costs
  - PHS 398 Modular Budget Form: within Additional Narrative Justification
Justifying DMS Budgets

• Brief summary of DMS Plan and description of DMS costs must be included within the budget justification attachment
  • R&R Budget Form: section L. Budget Justification
  • PHS 398 Modular Budget Form: Additional Narrative Justification
• NIH Institute & Center staff will determine if the DMS Plan is acceptable or unacceptable.

• Peer reviewers ONLY consider if the budget is reasonable. Comments from the peer reviewers regarding reasonableness will not affect the score.
Resolving Issues Before Award

- DMS Plan must be approved prior to NIH making an award.

- If additional details are needed, it may be necessary to communicate with NIH staff to resolve issues with DMS Plan:
  - Will occur through standard Just-In-Time (JIT) process.
  - Provide additional information and potentially a revised DMS Plan.
  - Work with your assigned Grant & Contract Officer to respond to such requests.
Monitoring Compliance

Approved Plan becomes a Term and Condition of Award

Grantee reports progress of approved DMS Plan in RPPR*

NIH reviews compliance annually

Failure to comply…. may result in an enforcement action, including additional special terms and conditions or termination of award, and may affect future funding decisions.

*RPPR: Research Performance Progress Report (RPPR) - Annual, Interim, and Final
Is my research also subject to other NIH data sharing policies?

DECISION TOOL

Which Policies Apply to My Research?

NIH has a variety of sharing policies in place for research that it funds. This tool will assist in helping you determine which of the following NIH policies apply to a particular project:

- Genomic Data Sharing Policy
- 2003 Data Sharing Policy
- Data Management & Sharing Policy (in effect January 25, 2023)
- Model Organism Sharing Policy
- Research Tools Policy

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NIH INSTITUTE AND CENTER DATA SHARING POLICIES

<table>
<thead>
<tr>
<th>Institute or Center</th>
<th>Data Sharing Policy Name</th>
<th>Description of Data Sharing Policy</th>
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<tr>
<td>NCI</td>
<td>NCI Clinical Trial Access Policy</td>
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NCI believes that the full value of NCI-supported Clinical Trials can be realized only if the results are published as rapidly as possible. The Clinical Trials Office is responsible for ensuring public availability of results from NCI-funded research grants, contracts, and/or clinical trial access agreements that support NCI-funded research grants, contracts, and/or clinical trial access agreements.
FDP DMS Demonstration Pilot Project

• Collaboration between the Federal Demonstration Partnership (FDP) membership, NIH Office of Policy for Extramural Research Administration (OPERA), NIH Institutes & Centers, and Open Education Resources groups.

• Goals of the DMS Demonstration Pilot:
  • Generate greater consistency in DMS Plan requirements across NIH ICs and programs.
  • Mitigate the administrative burden for researcher associated with DMS Plan development and implementation.

• Expected to run 9/1/2022 – 12/31/2023
FDP Pilot Timeline

Phase 1: Test Standardized DMS Plan Templates and DMPTool – 12/22-12/23

- Pilot participants will test the effectiveness of new web-based (DMPTool) templates to support the generation of a DMS Plan that is compliant with the new NIH policy and meets the varying needs of ICs.

Phase 2: Cost Policies – 1/23-12/23

- Establish common cost principles.
- Identify types of costs required.
- Determining how to identify additional/unforeseen costs that may be required to meet the spirit of the data sharing policy.
For More Information...

- **Website**: [NIH Scientific Data Sharing](https://www.nih.gov/sciencedatasharing)
- **FAQs**: [DMS Policy FAQs](https://dms.nih.gov/)
- **Email Box**: Sharing@nih.gov
- **Webinar Part II**: [Diving Deeper into the New NIH Data Management and Sharing Policy](https://www.nih.gov/)

[Image of NIH Scientific Data Sharing website]
For More Information...

• Policy References:

NOT-OD-21-013 – Final NIH Policy for Data Management and Sharing
NOT-OD-21-014 – Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan
NOT-OD-21-015 – Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing
NOT-OD-21-016 – Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research
NOT-OD-22-189 – Implementation Details for the NIH Data Management and Sharing Policy
NOT-OD-22-198 – Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023
eCommons

- Public access
- Persistent identifiers (Handle, DOI)
- Flexible, optional licenses
- Curatorial review
  [DCN member](https://ecommons.cornell.edu/)
- Links to and citations for related materials
- Versioning
- Long-term sharing and preservation

eCommons: [https://ecommons.cornell.edu/](https://ecommons.cornell.edu/)
Cornell Research Data Management Service Group

http://data.research.cornell.edu/  rdmsg-help@cornell.edu

Instruction and Best Practices

Decipher data licensing options

Find Appropriate Repositories

Data Life Cycle

DMP Consultation and Review

Analyze
Plan
Collect
Assure
Describe
Preserve
Discover
Integrate

Find Data Storage Services

Referrals to privacy, IP & patent law experts

Metadata Creation Assistance

eCommons@Cornell
Stay in the loop!

Join the RDMSG mailing list
Visit the RDMSG website
Email the RDMSG with questions
Thank you